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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,418	12/19/2001	Himanshu Patel	018489-002510US	2779
20350	7590	12/02/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			PANTUCK, BRADFORD C	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,418

Applicant(s)

PATEL ET AL.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/29/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-13, 24-39, 41-48, 61-72 and 74 is/are pending in the application.
- 4a) Of the above claim(s) 24-31 and 61 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6, 9-13, 32-39 and 41-48 is/are allowed.
- 6) ☒ Claim(s) 62, 69-72 and 74 is/are rejected.
- 7) ☒ Claim(s) 63-68 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

1. Claims 62-72 and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,638,233 B2 to Corvi et al.

The applied reference has a common assignee and a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

2. With regards to claims 62, 69-72, and 74, Corvi discloses in Figures 3 and 4 a method of debulking an artery, in accordance with the claimed invention. The catheter has a rotatable cutter (74) movable from an unexposed position to an exposed position and a collection chamber [the distal space inside of member (72)—adjacent to opening (76)]. The cutter rotates from a position inside the opening to a position in which it juts out of the opening [Fig. 4B]. Corvi discloses advancing the whole catheter distally (in direction (56)) [column 6, lines 1-6] to move the rotating cutter through occlusive material (as shown in Fig. 3B). The cutter and window maintain a

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fixed position relative to each other, i.e. they do not move relative to each other while the cutting is taking place.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 62, 69-72, and 74 are rejected under 35 U.S.C. 102(b) as anticipated by U.S. Patent No. 4,979,951 to Simpson or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 4,979,951 to Simpson. Regarding Claims 62 and 69, Simpson discloses a rotatable cutter (31), a distal collection chamber, and a cutting window. We know that there is a distal collection chamber because cutter (31) collects and pushes body tissue (93) distally [column 6, lines 13-20; see Fig. 2D].

Simpson discloses exposing the cutter, moving the cutter from the partially hidden configuration of Fig. 2B to the exposed (visible) position of Fig. 2C.

Simpson discloses advancing the catheter to the position shown in Fig. 2B *to* (that is, "for the reason of"/ "in order to") move the rotating cutter through occlusive material in the body lumen. Applicant should note that the claim language does not necessitate simultaneous movement of the whole catheter with a cutting action.

The cutter (31) is stored in Fig. 2B and slightly exposed in Fig. 2C. In one sense, during the cutting action illustrated in the progression from Fig. 2B to Fig. 2C to Fig.

2D, the cutter and window maintain their orientation to each other while the cutter is advanced through the occlusive material. During this whole cutting progression, the cutter *stays within the opening*, maintaining its *vertical orientation with respect to the window*.

In another sense, it would be *obvious* to a surgeon (of quite little skill in the art) to adjust the whole catheter system (as shown in Fig. 2C) by a couple of millimeters in order to align the catheter/cutter system perfectly with the proximal edge of an atheroma (93) before or after the balloon (67) is blown up. It will be quite unlikely that the catheter system will be perfectly aligned with the atheroma on the first insertion, and any surgeon would deem it obvious to adjust the whole catheter system to put the cutter in position.

Allowable Subject Matter

4. Claims 1-6, 9-13, 32-39, and 41-48 are allowed.
5. Claims 63-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,312,425 (column 5, lines 57-60: blade does not move relative to the catheter while cutting in one embodiment)

Response to Arguments

7. Applicant's arguments, see "REMARKS", filed September 29, 2004, with respect to the rejection(s) of claim(s) 62 and 69-72 under USC 103 (a) with U.S. Patent No. 4,966,604 to Reiss in view of U.S. Patent No. 6,022,362 to Lee et al. have been fully considered and are persuasive. Reiss does not disclose a collection chamber distal to the opening. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the patents described above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
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November 15, 2004

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ANH TUAN T. NGUYEN
PRIMARY EXAMINER

11/27/04